I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4).

Dated: October 1, 2009 Signature: /Lynn L. Janulis/ 53,066
(Lynn L. Janulis)

Docket No.: 28646/42100
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Hans J. Stauss et al.

Application No.: 10/581,773 Confirmation No.: 7037

Filed: February 12, 2007 Art Unit: 1644

For: Therapeutically Useful Molecules Examiner: Zachary S. Skelding

ELECTION, WITH TRAVERSE, IN RESPONSE TO RESTRICTION REQUIREMENT

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir/Madam:

In response to the restriction requirement set forth in the Office Action mailed April 1, 2009, Applicant hereby provisionally elects, **with traverse**, Group II (claims 12 and 13, directed to polynucleotides encoding the alpha or beta chain portions of the T cell receptor (TCR) molecule as defined in claim 1). Applicant also provisional elects, with traverse, the following species of alpha and beta chains for examination on the merits.

For the alpha chain, Applicant elects a chain having the following sequences:

CDR1: SSYSPS
CDR2: YTSAATL
CDR3: SPFSGGGADGLT

For the beta chain, Applicant elects a chain having the following sequences:

CDR1: DFQATT
CDR2: SNEGSKA
CDR3: RDGGEGSETQY

Applicant requests that the restriction requirement be reconsidered because the Examiner has not shown that a serious burden would be required to examine all of the claims and at least the claims in Groups II and III together. M.P.E.P. § 803 provides:

> If the search and examination of an application can be made without serious burden, the Examiner **must** examine it on the merits, even though it includes claims to distinct or independent inventions. (*Emphasis added.*)

Thus, for a restriction to be proper, the examiner must satisfy the following two criteria: (1) that independent and distinct inventions are being claimed (35 U.S.C. § 121); and (2) that the search and examination of the entire application cannot be made without serious burden. See M.P.E.P. § 803. Applicant submits that it would not be a burden for the Examiner to search and examine three claims, i.e. claims 12-14.

Applicant submits that the claim of Group III (claim 14, directed to a polynucleotide encoding the single chain TCR as defined in claim 7) should be examined together with the claims of Group II. The Examiner clarified, in a telephonic conversation with Applicant's undersigned representative on September 30, 2009, that claims 15-19 link the inventions of Groups II and III, and that the restriction between these two groups of inventions is subject to the non-allowance of linking claims 15-19. Applicant submits, however, that claim 14 is narrower than, and includes all of the features of, both claims 12 and 13. Thus, if it is not possible to have the claims of Groups II and III examined together, and thereby retain each of claims 12, 13, and 14 in their present form, Applicant submits that claim 14 will be amended to depend upon either one of claim 12 or claim 13. Such an amendment would clearly cause claim 14 to be part of the invention of Group II.

Moreover, the Examiner has alleged that the claims lack unity of invention under PCT Rule 13 in light of Stanislawski et al. (*Nat. Immunol.* 2:962-970, 2001; hereinafter "Stanislawski"). Applicant respectfully disagrees for at least the following reasons. Stanislawski apparently identified a T cell receptor (TCR) specific for the MDM2 cancer antigen. By contrast, the present claims all relate to a TCR that is specific for Wilms Tumour antigen-1 (WT1). The MDM2 antigen described in Stanislawski is not the same as the WT1 antigen described in the instant application. Stanislawski does not disclose or suggest a TCR for the WT1 cancer antigen; instead Stanislawski describes an unrelated TCR which targets a distinct antigen. Thus, the TCR described by Stanislawski would not combat WT1-

expressing cancer cells, but only MDM2-expressing cells. Thus, the description of a specific new TCR (as claimed in claim 1), which targets a distinct disease-related antigen (WT1), represents a single new, useful and non-obvious invention that provides the single general inventive concept required under PCT Rule 13.1.

The structure of a TCR is very similar to that of immunoglobulin Fab fragments. Functionally, TCRs are very similar to monoclonal antibodies in that they are able to bind antigens with a high degree of specificity based upon their sequence, especially that of the CDR regions of the TCR alpha and beta chains. Under U.S. patent law and practice, monoclonal antibodies that selectively bind to distinct antigens are always considered to be distinct inventions. Therefore, claims to the various aspects (e.g. polypeptide, polynucleotide, and methods of use) of a new monoclonal antibody binding to a specific antigen are not found to lack unity of invention under PCT Rule 13, based on the description of monoclonal antibodies that bind to unrelated antigens. In the same way, claims to the various aspects of a new TCR binding to a specific antigen should not be found to lack a single general inventive concept under PCT Rule 13.1 based on the description of a TCR that binds to an unrelated antigen.

Moreover, all of the claims of the present application are directed to a TCR with the specific CDR sequences listed in claim 1, or variants thereof. All of the claims share the special technical feature of CDRs defined by these sequences. The TCR of Stanislawski does not contain the CDR sequences listed in claim 1, or variants in which "up to three amino acids in one or more of the CDRs are replaced by another amino acid residue" (per claim 1), Since Stanislawski does not disclose or suggest the same special technical feature as the pending claims of the present application, Stanislawski cannot anticipate the invention and the claims fully meet the requirements of PCT Rule 13.2.

For all of the foregoing reasons, Applicant submits that the restriction is improper and should be withdrawn. Moreover, it would not be a serious burden for the Patent Office to at least examine the claims of Groups II and III together. Applicant reserves the right to rejoinder of non-elected claims that depend from or otherwise require all the limitations of an allowable claim. See M.P.E.P. § 821.04.